**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| MALLINCKRODT PHARMACEUTICALS IRELAND LIMITED and MALLINCKRODT HOSPITAL PRODUCTS IP UNLIMITED COMPANY,<br><br>Plaintiffs,<br><br>v.<br><br>AIRGAS THERAPEUTICS LLC, AIRGAS USA LLC, and AIR LIQUIDE S.A.,<br><br>Defendants. | C.A. No. _____<br>ANDA case |

## COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Mallinckrodt Pharmaceuticals Ireland Limited ("Mallinckrodt Ireland") and Mallinckrodt Hospital Products IP Unlimited Company ("Mallinckrodt Hospital") (collectively, "Mallinckrodt"), by their undersigned attorneys, bring this action against Defendants Airgas Therapeutics LLC ("Airgas"), Airgas USA LLC ("Airgas USA"), and Air Liquide S.A. ("Air Liquide") (collectively, "Defendants") and hereby allege as follows:

## NATURE OF THIS ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.,* arises from Defendants' submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 203144 ("Defendants' ANDA") seeking approval to market a generic version of Mallinckrodt's highly successful INOmax® therapy. Mallinckrodt lists U.S. Patent Nos. 9,770,570 ("the '570 patent"), 8,282,966 ("the '966 patent"), 8,293,284 ("the '284 patent"), 8,431,163 ("the '163 patent"), 8,795,741 ("'the '741 patent"), 8,291,904 ("the '904 patent"), 8,573,209 ("the '209 patent"), 8,573,210 ("the '210 patent"), 8,776,794 ("the '6,794 patent"), 8,776,795 ("the '795

patent"), 9,265,911 ("the '911 patent"), 9,279,794 ("the '9,794 patent"), 9,295,802 ("the '802 patent"), and 9,408,993 ("the '993 patent") in the FDA's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (collectively, the "Orange Book Patents").

## THE PARTIES

2. Plaintiff Mallinckrodt Ireland is a company organized and existing under the laws of Ireland, having a registered address of College Business & Technology Park, Cruiserath Road, Blanchardstown, Dublin 15, D15 TX2V, Ireland. Mallinckrodt Ireland is a wholly-owned, indirect subsidiary of Mallinckrodt plc. Mallinckrodt Ireland is the assignee of the Orange Book Patents.

3. Plaintiff Mallinckrodt Hospital is a company organized and existing under the laws of Ireland, having a registered address of College Business & Technology Park, Cruiserath Road, Blanchardstown, Dublin 15, D15 TX2V, Ireland. Mallinckrodt Hospital is a wholly-owned, indirect subsidiary of Mallinckrodt plc. As set forth herein, FDA records show that Mallinckrodt Hospital is the holder of New Drug Application ("NDA") No. 020845 for INOmax®, 800 ppm.

4. On information and belief, Defendant Airgas is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 6141 Easton Rd. Building 3, Plumsteadville, PA 18949.

5. On information and belief, Airgas is in the business of manufacturing and supplying specialty medical gases, including nitric oxide, and systems and equipment for the same, for sale and/or use throughout the United States, including in this Judicial District.

6. On information and belief, and as supported by Airgas's website, Airgas holds itself out as an Air Liquide company.

7. On information and belief, Defendant Airgas USA is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business

at 259 N. Radnor Chester Road, Suite 100, Radnor, PA 19087. On information and belief, Airgas is a wholly-owned subsidiary of Airgas USA.

8. On information and belief, Airgas USA is leading single-source supplier and distributor of medical and other specialty gases.

9. On information and belief, and as supported by Airgas USA's website, Airgas USA holds itself out as an Air Liquide company.

10. On information and belief, Defendant Air Liquide is a corporation organized and exiting under the laws of France, with a principal place of business at 75 Quai D Orsay, Paris Cedex 07, Paris, 75321. On information and belief, Airgas and Airgas USA are wholly-owned subsidiaries of Air Liquide.

11. On information and belief, Air Liquide is in the business of producing and preserving pharmaceutical products, as well as pharmaceutical formulation, packaging and distribution.

12. On information and belief, Defendants are agents of one another and/or operate in concert as integrated parts of the same business group.

13. On information and belief, Airgas, itself and/or through Airgas USA and/or Air Liquide, is in the business of developing, manufacturing, marketing, and/or selling medical gases and/or equipment for the same throughout the United States, including in this Judicial District.

14. On information and belief, Airgas USA, itself and/or through Airgas and/or Air Liquide, is in the business of developing, manufacturing, marketing, and/or selling medical gases and/or equipment for the same throughout the United States, including in this Judicial District.

15. On information and belief, Air Liquide, itself and/or through Airgas and/or Airgas USA, is in the business of developing, manufacturing, marketing, and/or selling medical gases and/or equipment for the same throughout the United States, including in this Judicial District.

16. On information and belief, and as described in Defendants' written notification of Defendants' ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certifications received November 18, 2022 ("Defendants' Paragraph IV Notice Letter"), Defendants caused Defendants' ANDA to be submitted to FDA and seek FDA approval of Defendants' ANDA prior to the expiration of the Orange Book Patents.

17. On information and belief, Defendants intend, prior to the expiration of the Orange Book Patents, to commercially manufacture, use, offer for sale, sell, and/or import into the United States the proposed generic Nitric Oxide Gas for Inhalation, 800 ppm described in Defendants' ANDA ("Defendants' Proposed ANDA Product") throughout the United States, including in the State of Delaware, upon receiving FDA approval of Defendants' ANDA.

## JURISDICTION AND VENUE

18. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 1291, 1400, and 2201(a).

19. This Court has personal jurisdiction over Defendants by virtue of, *inter alia,* on information and belief, Defendants having availed themselves of the rights and benefits of the laws of the State of Delaware by engaging in substantial, continuous, and systematic contacts with the State of Delaware and because Defendants intend to indirectly or directly make, use, offer for sale, sell, and/or import specialty medical gases and/or systems for the use thereof, including Defendants' Proposed ANDA Product, to residents of the State of Delaware. Accordingly, Defendants should reasonably anticipate being hauled into court in this Judicial District.

20. On information and belief, Airgas, Airgas USA, and/or Air Liquide, acting in concert and/or as agents of one another, prepared and/or submitted and/or approved of Defendants' ANDA.

21. On information and belief, the acts of Airgas, including the development of Defendants' Proposed ANDA Product and the preparation and submission of Defendants' ANDA, complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation or assistance of, or at least in part for the benefits of Airgas USA and Air Liquide.

22. On information and belief, Airgas, Airgas USA, and/or Air Liquide, acting in concert and/or as agents of one another, will market, distribute, and/or sell Defendants' Proposed ANDA Product in the United States, including in the State of Delaware, upon approval of Defendants' ANDA, and will derive substantial revenue from the sale of Defendants' Proposed ANDA Product.

23. On information and belief, Defendants' Proposed ANDA Product will be used within and throughout the United States, including the State of Delaware.

24. On information and belief, Defendants' Proposed ANDA Product will be prescribed by physicians and/or health care providers and/or will be used by patients in the State of Delaware.

25. This Court also has personal jurisdiction over Defendants by virtue of, *inter alia*, the fact that they have committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led to and/or will lead to foreseeable harm and injury to Mallinckrodt.

26. This Court has personal jurisdiction over Airgas and Airgas USA by virtue of the fact that Airgas and Airgas USA are at home in Delaware as reflected by the fact that they are incorporated in Delaware, regularly do and/or solicit business in Delaware, engage in other persistent courses of conduct in Delaware, and/or derive substantial revenue from services or things used or consumed in Delaware, including by distributing its specialty medical gases, equipment, and/or systems in Delaware and, therefore, can reasonably expect to be subject to jurisdiction in the Delaware courts. Among other things, upon information and belief, Airgas and Airgas USA conduct marketing and sales activities in the State of Delaware, including, but not limited to, distribution, marketing, and/or sales of specialty medical gases, equipment, and/or systems to Delaware residents that are continuous and systemic. Additionally, upon information and belief, Airgas and Airgas USA intend to distribute, market, and/or sell the proposed Airgas ANDA Product in the State of Delaware.

27. This Court has personal jurisdiction over Air Liquide pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Air Liquide is a foreign defendant who appears not to be subject to personal jurisdiction in the courts of any state; and (c) Air Liquide has sufficient contacts with the United States as a whole, including, but not limited to, submitting various ANDAs to the FDA, and manufacturing, selling, and/or distributing medical gases and/or equipment throughout the United States, such that this Court's exercise of jurisdiction over Air Liquide satisfies due process.

28. Venue is proper in this Court for Airgas and Airgas USA pursuant to 28 U.S.C. § 1400(b) because, on information and belief, *inter alia,* Airgas and Airgas USA are limited liability companies organized under the laws of the State of Delaware and, therefore, reside in this Judicial District.

29. Venue is proper in this Judicial District for Air Liquide pursuant to 28 U.S.C. §§ 1391 and/or 1400 because, on information and belief, *inter alia*, Air Liquide is a company organized and existing under the laws of France, and may be sued in any judicial district pursuant to 28 U.S.C. § 1391(c) and Defendants' Proposed ANDA Product will be prescribed by physicians and/or health care providers and/or will be used by patients in the State of Delaware. Each of these activities would have a substantial effect within the State of Delaware and would constitute an act of infringement if Defendants' Proposed ANDA Product is approved.

30. Venue is further proper against Defendants as they are the alter egos and/or agents of each other (which are all individually also subject to venue in this Judicial District) in connection with the submission of Defendants' ANDA.

## INOMAX® AND BACKGROUND OF THE INVENTIONS

31. FDA records show that Mallinckrodt Hospital holds approved NDA No. 020845 for its Nitric Oxide Gas for Inhalation, 800 ppm product. FDA approved NDA No. 020845 in December 1999 for administration by inhalation to neonates and children suffering from hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension. Mallinckrodt's nitric oxide 800 ppm for inhalation product is sold in the United States under the trademark INOmax®. FDA records also show Mallinckrodt obtained approval for a specialized, highly sophisticated delivery system called INOmax® DS, INOmax® DSIR, and INOmax® DSIR Plus, which were approved by FDA starting in December 2006. Since their approval by FDA, INOmax®, INOmax® DS, INOmax® DSIR, and INOmax® DSIR Plus have becomes highly successful, life-sustaining therapies.

32. Mallinckrodt has obtained a number of patents directed to inventions related to the administration and delivery of nitric oxide, associated systems, devices, and processes, and methods of treatment, for INOmax®.

33. Certain of the Orange Book Patents are broadly directed to systems and devices for the administration of nitric oxide, and associated methods and processes. The remainder of the Orange Book Patents are broadly directed to methods of treating patients with nitric oxide while reducing the risks of adverse events or serious adverse events ("SAEs") associated with nitric oxide treatment. The method of treatment patents disclose a solution to the previously unknown problem that neonates and children suffering from hypoxic respiratory failure who also suffer from pre-existing left ventricular dysfunction ("LVD") have a high risk of experiencing SAEs such as pulmonary edema if they are administered nitric oxide. These patents recite methods of reducing the risks of SAEs associated with administering nitric oxide by determining whether the patients have pre-existing LVD, and adjusting the administration of nitric oxide based on the patient's LVD status.

34. The invention of the Orange Book Patents are embodied in at least Mallinckrodt's INOmax® drug product, and one or more of the associated delivery systems, and their methods and conditions of use. The FDA approved labeling for INOmax® reflects the inventions of the Orange Book Patents, and is covered by the claims of the Orange Book Patents, in that it informs the prescribers, health care providers, and/or patients that "[i]n patients with pre-existing [LVD], [INOmax®] may increase pulmonary capillary wedge pressure leading to pulmonary edema." INOmax® Label at 1, attached as Exhibit 15. Consequently, prescribers, health care providers, and/or patients of INOmax® are instructed to identify patients with LVD, and to affirmatively and actively adjust the dosing of INOmax® based on whether patients have LVD and the resulting risk of pulmonary edema. *See id*. at 1; *see also id.* at 3.

35. Certain of the Orange Book Patents, specifically the '741 patent, '966 patent, '284 patent, '163 patent, '6,794 patent, '795 patent, '209 patent, '911 patent, '802 patents, and '9,794

patent, were previously asserted in *Mallinckrodt Hospital Products IP LTD. v. Praxair Distribution, Inc.*, C.A. No. 1:15-cv-00170-RGA (D. Del.) ("*Praxair* litigation"). There, the District Court of Delaware entered a judgment that only claim 20 of the '966 patent, only claim 18 of the '284 patent, only claims 9, 11, 13, and 15 of the '163 patent, and only claims 1, 4, 7, 9, and 18 of the '741 patent were invalid under 35 U.S.C. § 101. *Id*. at D.I. 322.

36. At least claims 24-30, and 33 of the '741 patent are not invalid in light of the prior judgment in the *Praxair* litigation because they were not subject to the judgment in the *Praxair* litigation and they include an affirmative treatment step, including adjusting the administration of nitric oxide based on the patient's LVD status.

## THE ORANGE BOOK PATENTS

37. On September 26, 2017, the United States Patent and Trademark Office ("PTO") duly and legally issued the '570 patent, titled "Apparatus and method for monitoring nitric oxide delivery." Each and every claim of the '570 patent is valid and enforceable. A true and correct copy of the '570 patent is attached as Exhibit 1.

38. The '570 patent is assigned to Mallinckrodt Ireland.

39. The '570 patent is listed in the Orange Book for INOmax®.

40. Claim 1 of the '570 patent recites:

> A method of monitoring the delivery of therapeutic gas to a patient comprising:
>
> receiving to a gas delivery device a desired concentration of therapeutic gas;
>
> providing a flow of breathing gas;
>
> providing a flow of therapeutic gas comprising nitric oxide;
>
> delivering a combined flow of the breathing gas and the therapeutic gas to a patient;
>
> measuring via a first flow sensor a measured flow rate of the breathing gas;

> obtaining a flow rate of the therapeutic gas that is one of a measured flow rate and a known flow rate;
>
> determining, using the flow rate of the therapeutic gas and the flow rate of the breathing gas, a calculated delivered concentration of therapeutic gas in the combined flow; and
>
> presenting on a display a visual indication of the calculated delivery concentration of nitric oxide as a percentage comparison to the desired delivery concentration, wherein the visual indication includes a first region representing over delivery and a second region representing under delivery wherein the visual indicator further includes a marker associated with one of the first region and second region.

(Exhibit 1).

41. On October 9, 2012, the PTO duly and legally issued the '966 patent, titled "Methods of reducing the risk of occurrence of pulmonary edema in children in need of treatment with inhaled nitric oxide." At least claims 1-12, 14-19, and 21-29 of the '966 patent are valid and enforceable. A true and correct copy of the '966 patent is attached as Exhibit 2.

42. The '966 patent is assigned to Mallinckrodt Ireland.

43. The '966 patent is listed in FDA's Orange Book for INOmax®.

44. Claim 1 of the '966 patent recites:

> A method of reducing the risk of occurrence of pulmonary edema associated with a medical treatment comprising inhalation of 20 ppm nitric oxide gas, said method comprising:
>
> (a) performing echocardiography to identify a child in need of 20 ppm inhaled nitric oxide treatment for pulmonary hypertension, wherein the child is not dependent on right-to-left shunting of blood;
>
> (b) determining that the child identified in (a) has a pulmonary capillary wedge pressure greater than or equal to 20 mm Hg and thus has left ventricular dysfunction, so is at particular risk of pulmonary edema upon treatment with inhaled nitric oxide; and
>
> (c) excluding the child from inhaled nitric oxide treatment based on the determination that the child has left ventricular dysfunction and so is at particular risk of pulmonary edema upon treatment with inhaled nitric oxide.

(Exhibit 2).

45. On October 23, 2012, the PTO duly and legally issued the '284 patent, titled "Methods of reducing the risk of occurrence of pulmonary edema in term or near-term neonates in need of treatment with inhaled nitric oxide." At least claims 1-12, 14-17, and 19-30 of the '284 patent are valid and enforceable. A true and correct copy of the '284 patent is attached as Exhibit 3.

46. The '284 patent is assigned to Mallinckrodt Ireland.

47. The '284 patent is listed in FDA's Orange Book for INOmax®.

48. Claim 1 of the '284 patent recites:

> A method of reducing the risk of occurrence of pulmonary edema associated with a medical treatment comprising inhalation of 20 ppm nitric oxide gas, said method comprising:
>
> (a) performing echocardiography to identify a term or near-term neonate patient in need of 20 ppm inhaled nitric oxide treatment for pulmonary hypertension, wherein the patient is not dependent on right-to-left shunting of blood;
>
> (b) determining that the patient identified in (a) has a pulmonary capillary wedge pressure greater than or equal to 20 mm Hg and thus has left ventricular dysfunction, so is at particular risk of pulmonary edema upon treatment with inhaled nitric oxide; and
>
> (c) excluding the patient from inhaled nitric oxide treatment based on the determination that the patient has left ventricular dysfunction and so is at particular risk of pulmonary edema upon treatment with inhaled nitric oxide.

(Exhibit 3).

49. On April 30, 2013, the PTO duly and legally issued the '163 patent, titled "Methods of reducing the risk of occurrence of pulmonary edema associated with inhalation of nitric oxide gas." At least claims 1-5, 7, 8, 10, 14, and 16-25 of the '163 patent are valid and enforceable. A true and correct copy of the '163 patent is attached as Exhibit 4.

50. The '163 patent is assigned to Mallinckrodt Ireland.

51. The '163 patent is listed in FDA's Orange Book for INOmax®.

52. Claim 1 of the '163 patent recites:

> A method of reducing the risk of occurrence of pulmonary edema associated with a medical treatment comprising inhalation of 20 ppm nitric oxide gas, said method comprising:
>
> (a) performing echocardiography to identify a term or near-term neonate patient in need of 20 ppm inhaled nitric oxide treatment for hypoxic respiratory failure, wherein the patient is not dependent on right-to-left shunting of blood;
>
> (b) determining that the patient identified in (a) has left ventricular dysfunction consistent with a pulmonary capillary wedge pressure greater than or equal to 20 mm Hg, so is at particular risk of pulmonary edema upon treatment with inhaled nitric oxide; and
>
> (c) excluding the patient from inhaled nitric oxide treatment, based on the determination that the patient has left ventricular dysfunction and so is at particular risk of pulmonary edema upon treatment with inhaled nitric oxide.

(Exhibit 4).

53. On August 5, 2014, the PTO duly and legally issued the '741 patent, titled "Methods for treating patients who are candidates for inhaled nitric oxide treatment." At least claims 2, 3, 5, 6, 8, 10-16, and 19-44 of the '741 patent are valid and enforceable. A true and correct copy of the '741 patent is attached as Exhibit 5.

54. The '741 patent is assigned to Mallinckrodt Ireland.

55. The '741 patent is listed in FDA's Orange Book for INOmax®.

56. Claim 24 of the '741 patent recites:

> A method of treating patients who are candidates for inhaled nitric oxide treatment, which method reduces the risk of inducing an increase in PCWP leading to pulmonary edema in neonatal patients with hypoxic respiratory failure, the method comprising:
>
> (a) identifying a plurality of term or near-term neonatal patients who have hypoxic respiratory failure and are candidates for 20 ppm inhaled nitric oxide treatment;
>
> (b) determining that a first patient of the plurality does not have pre-existing left ventricular dysfunction;
>
> (c) administering a first treatment regimen to the first patient, wherein the first treatment regimen comprises administration of 20 ppm inhaled nitric oxide for 14 days or until the first patient's hypoxia has resolved;

(d) determining that a second patient of the plurality has pre-existing left ventricular dysfunction, so is at particular risk of increased PCWP leading to pulmonary edema upon treatment with inhaled nitric oxide; and

(e) administering a second treatment regimen to the second patient, wherein the second treatment regimen does not comprise either (i) administration of inhaled nitric oxide for 14 days or (ii) administration of inhaled nitric oxide until the second patient's hypoxia has resolved.

(Exhibit 5).

57. At least claim 24 of the '741 patent, and the claims that depend therefrom, are materially different from the claims in the *Praxair* litigation because claim 24 recites an affirmative step of treating the patient that suffers from pre-existing left ventricular dysfunction, including adjusting the dose of inhaled nitric oxide treatment in the patient.

58. On October 23, 2012, the PTO duly and legally issued the '904 patent, titled "Gas delivery device and system." Each and every claim of the '904 patent is valid and enforceable. A true and correct copy of the '904 patent is attached as Exhibit 6.

59. The '904 patent is assigned to Mallinckrodt Ireland.

60. The '904 patent is listed in FDA's Orange Book for INOmax®.

61. Claim 1 of the '904 patent recites:

A valve assembly to deliver a gas comprising NO from a gas container containing the gas comprising NO, the valve assembly comprising:

a valve attachable to the gas container containing the gas comprising NO, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas comprising NO through the valve to a control module;

a circuit supported within the valve assembly and disposed between the actuator and a cap, the circuit including:

a valve memory to store gas data comprising gas concentration in the gas container and

a valve processor and a valve transceiver in communication with the valve memory to send wireless optical line-of-sight signals to communicate the gas data to the control module that controls gas delivery to a subject; and

a data input disposed on the actuator and in communication with said valve memory, to permit a user to enter the gas data into the valve memory.

(Exhibit 6).

62. On November 5, 2013, the PTO duly and legally issued the '209 patent, titled "Gas delivery device and system." Each and every claim of the '209 patent is valid and enforceable. A true and correct copy of the '209 patent is attached as Exhibit 7.

63. The '209 patent is assigned to Mallinckrodt Ireland.

64. The '209 patent is listed in FDA's Orange Book for INOmax®.

65. Claim 1 of the '209 patent recites:

A gas delivery device to administer therapy gas from a gas source, the gas delivery device comprising:

a valve attachable to the gas source, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas through the valve to a control module; and

a circuit including:

memory to store gas data comprising one or more of gas identification, gas expiration date and gas concentration and

a processor and a transceiver in communication with the memory to send and receive wireless optical line-of-sight signals to communicate the gas data to the control module that controls gas delivery to a subject and to verify one or more of the correct gas, the correct gas concentration and that the gas is not expired,

wherein the valve further comprises a data input in communication with said memory, to permit a user to enter the gas data into the memory.

(Exhibit 7).

66. On November 5, 2013, the PTO duly and legally issued the '210 patent, titled "Nitric oxide delivery device." Each and every claim of the '210 patent is valid and enforceable. A true and correct copy of the '210 patent is attached as Exhibit 8.

67. The '210 patent is assigned to Mallinckrodt Ireland.

68. The '210 patent is listed in FDA's Orange Book for INOmax®.

69. Claim 1 of the '210 patent recites:

A nitric oxide delivery device comprising:

a control module to deliver a gas comprising NO to a patient in an amount effective to treat or prevent hypoxic respiratory failure; and

a valve assembly to deliver the gas comprising NO from a gas container containing the gas comprising NO to the control module, the valve assembly comprising:

a valve attachable to the gas container containing the gas comprising NO, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas comprising NO through the valve to the control module; and

a circuit supported within the valve assembly and disposed between the actuator and a cap, the circuit including:

a valve memory to store gas data comprising one or more of gas identification, gas expiration date and gas concentration in the gas container and

a valve processor and a valve transceiver in communication with the valve memory to send and receive wireless optical line-of-sight signals to communicate the gas data to the control module and to verify one or more of the correct gas, the correct gas concentration and that the gas is not expired.

(Exhibit 8).

70. On July 15 2014, the PTO duly and legally issued the ’6,794 patent, titled “Nitric oxide delivery device.” Each and every claim of the ’6,794 patent is valid and enforceable. A true and correct copy of the ’6,794 patent is attached as Exhibit 9.

71. The ’6,794 patent is assigned to Mallinckrodt Ireland.

72. The ’6,794 patent is listed in FDA’s Orange Book for INOmax®.

73. Claim 1 of the ’6,794 patent recites:

A gas delivery device comprising:

a gas source to provide therapy gas comprising nitric oxide;

a valve attachable to the gas source, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas through the valve to a control module that delivers the therapy gas comprising nitric oxide in an amount effective to treat or prevent hypoxic respiratory failure; and

a circuit including:

> a memory to store gas data comprising one or more of gas identification, gas expiration date and gas concentration; and
>
> a processor and a transceiver in communication with the memory to send and receive signals to communicate the gas data to the control module that controls gas delivery to a subject and to verify one or more of the gas identification, the gas concentration and that the gas is not expired.

(Exhibit 9).

74. On July 15, 2014, the PTO duly and legally issued the '795 patent, titled "Gas delivery device and system." Each and every claim of the '795 patent is valid and enforceable. A true and correct copy of the '795 patent is attached as Exhibit 10.

75. The '795 patent is assigned to Mallinckrodt Ireland.

76. The '795 patent is listed in FDA's Orange Book for INOmax®.

77. Claim 1 of the '795 patent recites:

> A gas delivery device to administer therapy gas from a gas source, the gas delivery device comprising:
>
> a valve attachable to the gas source, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas through the valve; and
>
> a circuit including:
>
> a memory to store gas data comprising one or more of gas identification, gas expiration date and gas concentration; and
>
> a processor and a transceiver in communication with the memory to send and receive signals to communicate the gas data to a control module that controls gas delivery to a subject and to verify one or more of the gas identification, the gas concentration and that the gas is not expired.

(Exhibit 10).

78. On February 23, 2016, the PTO duly and legally issued the '911 patent, titled "Gas delivery device and system." Each and every claim of the '911 patent is valid and enforceable. A true and correct copy of the '911 patent is attached as Exhibit 11.

79. The '911 patent is assigned to Mallinckrodt Ireland.

80. The '911 patent is listed in FDA's Orange Book for INOmax®.

81. Claim 1 of the ’911 patent recites:

A therapy gas delivery system comprising:

a device comprising:

a drug source; and

a circuit comprising:

a first memory to store drug data comprising one or more of drug identification, drug expiration date and drug concentration of the drug source; and

a first processor and a first transceiver in communication with the first memory; and

a control module that controls delivery of therapy gas to a subject by delivering therapy gas to a ventilator circuit, the control module comprising a second memory, a second transceiver and a second processor, wherein the second transceiver and the second processor are in communication with the second memory,

wherein the first transceiver and the second transceiver send and receive signals to communicate the drug data to the control module and to verify one or more of the drug identification, the drug concentration and that the drug is not expired.

(Exhibit 11).

82. On March 8, 2016, the PTO duly and legally issued the ’9,794 patent, titled “Systems and methods for compensating long term sensitivity drift of electrochemical gas sensors exposed to nitric oxide.” Each and every claim of the ’9,794 patent is valid and enforceable. A true and correct copy of the ’9,794 patent is attached as Exhibit 12.

83. The ’9,794 patent is assigned to Mallinckrodt Ireland.

84. The ’9,794 patent is listed in FDA’s Orange Book for INOmax®.

85. Claim 1 of the ’9,794 patent recites:

A method for compensating for output drift of an electrochemical gas sensor exposed to nitric oxide in a controlled environment comprising:

establishing, via a setting in a system controller, a dosage of a nitric oxide to be delivered to a patient;

delivering, via a flow control valve, a therapeutic gas comprising nitric oxide to a breathing circuit for delivery to the patient;

identifying a change in the setting the system controller;

identifying, via the system controller, a sensor recalibration schedule stored in a system controller memory in response to the identified change;

identifying, via the system controller, a time for executing a calibration from the sensor recalibration schedule stored in the system controller memory;

detecting, via the system controller, if an alarm is active or has been active within a predetermined timeframe at the time the calibration is to be executed, wherein the calibration is postponed if the active alarm is detected or has been detected within the predetermined timeframe, and the calibration is executed if the active alarm is not detected or has not been detected within the predetermined timeframe;

implementing, via the system controller, the sensor recalibration schedule identified;

continuously measuring, via a first nitric oxide sensor, a concentration of the nitric oxide in the breathing circuit;

communicating a signal representative of the nitric oxide concentration from the first nitric oxide sensor to the system controller over a communication path; and

determining a response by the first nitric oxide sensor to the nitric oxide concentration after the change in the setting in the system controller.

(Exhibit 12).

86. On March 29, 2016, the PTO duly and legally issued the ’802 patent, titled “Gas delivery device and system.” Each and every claim of the ’802 patent is valid and enforceable. A true and correct copy of the ’802 patent is attached as Exhibit 13.

87. The ’802 patent is assigned to Mallinckrodt Ireland.

88. The ’802 patent is listed in FDA’s Orange Book for INOmax®.

89. Claim 1 of the ’802 patent recites:

A therapy gas delivery system comprising:

a device comprising:

a drug source;

a first memory to store drug data comprising one or more of drug identification,

drug expiration date and drug concentration of the drug source; and

a first transceiver in communication with the first memory; and

a control module that controls delivery of therapy gas to a subject by delivering therapy gas to a ventilator circuit, the control module comprising a second memory and a second transceiver, wherein the second transceiver is in communication with the second memory,

wherein the first transceiver and the second transceiver send and receive signals to communicate the drug data to the control module and to verify one or more of the drug identification, the drug concentration and that the drug is not expired.

(Exhibit 13).

90. On August 9, 2016, the PTO duly and legally issued the '893 patent, titled "Nitric oxide delivery device." Each and every claim of the '993 patent is valid and enforceable. A true and correct copy of the '993 patent is attached as Exhibit 14.

91. The '993 patent is assigned to Mallinckrodt Ireland.

92. The '993 patent is listed in FDA's Orange Book for INOmax®.

93. Claim 1 of the '993 patent recites:

A therapy gas delivery system comprising:

a device comprising:

a drug source; and

a circuit comprising:

a first memory to store drug data comprising one or more of drug identification, drug expiration date and drug concentration of the drug source; and

a first processor and a first transceiver in communication with the first memory; and

a control module that delivers therapy gas comprising nitric oxide in an amount effective to treat or prevent hypoxic respiratory failure, the control module comprising a second memory, a second transceiver and a second processor, wherein the second transceiver and the second processor are in communication with the second memory, wherein the first transceiver and the second transceiver send and receive signals to communicate the drug data to the control module and to verify one or more of the drug identification, the drug concentration and that the drug is not expired.

(Exhibit 14).

**DEFENDANTS' ARTIFICAL ACT OF INFRINGEMENT**

94. On information and belief, Defendants' Paragraph IV Notice Letter indicates that Defendants submitted and continues to maintain Defendants' ANDA to FDA under 21 U.S.C. § 355(j).

95. On information and belief, and based on Defendants' Notice Paragraph IV Notice Letter, Defendants submitted Defendants' ANDA to FDA in order to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product, as a purported generic version of INOmax® prior to the expiration of the Orange Book Patents.

96. On information and belief, FDA has not yet approved Defendants' ANDA.

97. Defendants' Paragraph IV Notice Letter states that "[Defendants seeks] to obtain approval to engage in the commercial manufacture, use or sale of [Defendants' Proposed ANDA Product], 800 ppm, before the expiration of the '966 patent, '904 patent, '284 patent, '163 patent, '209 patent, '210 patent, '794 patent, '795 patent, '741 patent, '112 patent, '911 patent, '9,794 patent, '802 patent, '993 patent, and '570 patent, all of which are listed in the Patent and Exclusivity Information Addendum of FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as 'the Orange Book') … FDA is aware that Airgas Therapeutics is only seeking approval for the 800 ppm strength."

98. On information and belief, and as supported by Defendants' Paragraph IV Notice Letter, by filing Defendants' ANDA, Defendants certified to FDA that Defendants' Proposed ANDA Product has the same active pharmaceutical ingredient as INOmax®.

99. On information and belief, and as supported by Defendants' Paragraph IV Notice Letter, by filing Defendants' ANDA, Defendants certified to FDA that Defendants' Proposed ANDA Product has the same dosage form and strength as INOmax®.

100. On information and belief, and as supported by Defendants' Paragraph IV Notice Letter, by filing Defendants' ANDA, Defendants certified to FDA that Defendants' Proposed ANDA Product is bioequivalent to INOmax®.

101. On information and belief, Defendants are seeking approval to market Defendants' Proposed ANDA Product for the same approved indication as INOmax®.

102. On information and belief, Defendants' ANDA contains either the same or substantially similar proposed product labeling as INOmax®.

103. In Defendants' Paragraph IV Notice Letter, Defendants offered confidential access to portions of its ANDA No. 203144, on overly restrictive terms and conditions ("the Airgas Offer"). Airgas demanded that Mallinckrodt accept the Airgas Offer before receiving access to Defendants' ANDA. The Airgas Offer contained unreasonable restrictions well beyond those provided by statute and those that would typically apply under a protective order on, for example, which individuals could view the ANDA. For example, the Airgas Offer provides access only to attorneys from one outside law firm representing Mallinckrodt, and expressly prohibited any scientific experts or consultants from viewing the ANDA. The Airgas Offer contained a broad and vague patent prosecution and FDA bar, which, among other things, sought to prohibit access to counsel that engage, formally or informally, in any patent prosecution for Mallinckrodt or any FDA counseling, litigation, or other work before or involving FDA. The Airgas Offer unreasonably restricted the ability of counsel to seek the opinions of Mallinckrodt's employees and outside experts. The restrictions Airgas has placed on access to ANDA No. 203144 contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, *as would apply had a protective order been entered for*

*the purpose of protecting trade secrets and other confidential business information*" (emphasis added).

104. To date, Defendants have not provided access to Defendants' ANDA.

105. At least in view of Defendants' representations and admissions based on the Defendants' Paragraph IV Notice Letter, Mallinckrodt has a good faith basis to believe that Defendants have infringed, are infringing, and will infringe at least one of the Orange Book Patents.

106. Defendants' Paragraph IV Notice Letter represents that Defendants' ANDA contains a certification under 21 U.S.C. § 355(j)(2)(B)(iv)(II) (the "Paragraph IV certification") alleging that the claims of the Orange Book Patents are invalid or would not be infringed by the commercial manufacture, use, offer for sale, sale, or importation of Defendants' Proposed ANDA Product.

107. Defendants' submission of Defendants' ANDA to FDA, including their Paragraph IV certification, constitutes an act of infringement under 35 U.S.C. § 271(e)(2)(A). In the event that Defendants commercially manufacture, use, offer for sale, sell, and/or import into the United States the Defendants' Proposed ANDA Product or induces or contributes to such conduct, said actions would constitute infringement under 35 U.S.C. § 271(a), (b), and/or (c).

108. Upon information and belief, Defendants were aware, and had notice, of the Orange Book Patents prior to filing Defendants' ANDA, and their willful actions render this an exceptional case under 35 U.S.C. § 285.

109. The acts of infringement by Defendants set forth above will cause Mallinckrodt irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

110. Mallinckrodt has filed this complaint within 45 days of receiving Defendants' Paragraph IV Notice Letter.

111. Mallinckrodt hereby alleges that Defendants' filing of its ANDA infringes at least U.S. Patent Nos. 9,770,570 ("the '570 patent"), 8,291,904 ("the '904 patent"), 8,573,209 ("the '209 patent"), 8,573,210 ("the '210 patent"), 8,776,794 ("the '6,794 patent"), 8,776,795 ("the '795 patent"), 9,265,911 ("the '911 patent"), 9,279,794 ("the '9,794 patent"), 9,295,802 ("the '802 patent"), 8,795,741 ("the '741 patent") and 9,408,993 ("the '993 patent") (collectively, the "Patents-in-Suit").

**COUNT I FOR PATENT INFRINGEMENT**
**(Infringement of the '570 Patent under 35 U.S.C. § 271(e)(2))**

112. Plaintiffs incorporate by reference paragraphs 1-111 as if fully set forth herein.

113. On information and belief, Defendants submitted Defendants' ANDA to FDA, and thereby seek FDA approval of Defendants' Proposed ANDA Product.

114. Defendants' Proposed ANDA Product infringes one or more claims of the '570 patent.

115. Defendants have infringed one or more claims of the '570 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA and thereby seeking FDA approval of a generic version of INOmax®, prior to the expiration of the '570 patent.

116. On information and belief, the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product prior to the expiration of the '570 Patent would infringe one or more claims of the '570 patent under 35 U.S.C. § 271(a), and/or Defendants would induce and/or contribute to the infringement of one or more claims of the '570 patent under 35 USC § 271(b) and/or (c).

117. Upon information and belief, Defendants had actual and/or constructive notice of the '570 Patent since its publication on September 26, 2017, and nonetheless maintained Defendants' ANDA despite being aware that the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product prior to the expiration of the '570 patent would constitute an act of infringement.

118. Mallinckrodt will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '570 patent. Mallinckrodt does not have an adequate remedy at law and, considering the balance of hardships between Mallinckrodt and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

119. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '570 patent, actively inducing infringement of the '570 patent, and/or contributing to the infringement by others of the '570 patent.

120. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

**COUNT II FOR DECLARATORY JUDGMENT**
**(Declaratory Judgement of Patent Infringement of the '570 Patent under 35 U.S.C. § 271 (a), (b), and/or (c))**

121. Plaintiffs incorporate by reference paragraphs 1-120 as if fully set forth herein.

122. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

123. On information and belief, if FDA approves Defendants' Proposed ANDA Product for use and sale in the United States, Defendants would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '570 patent under 35 U.S.C. §

271(a), in violation of Mallinckrodt's patent rights, by making, using, offering to sell, selling, and/or importing Defendants' Proposed ANDA Product for use and sale within the United States.

124. The manufacture, use, offer for sale, sale, and/or importation of Defendants' Proposed ANDA Product so labeled, if approved by FDA, will induce and/or contribute to the infringement of one or more claims of the '570 patent under 35 U.S.C. §§ 271(b) and/or (c), in violation of Mallinckrodt's patent rights.

125. On information and belief, Defendants have knowledge of the '570 patent and filed Defendants' ANDA seeking authorization to commercially manufacture, use, offer for sale, sell, and/or import into the United States Defendants' Proposed ANDA Product. On information and belief, if FDA approves Defendants' ANDA, physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '570 patent.

126. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the '570 patent with the requisite intent under 35 U.S.C. § 271(b).

127. On information and belief, if FDA approves Defendants' ANDA, Defendants will sell or offer to sell Defendants' Proposed ANDA Product specifically labeled for use in practicing one or more of the claims of the '570 patent, wherein Defendants' Proposed ANDA Product is a material part of the inventions claimed in the '570 patent, wherein Defendants know that physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product for one or more of the inventions in the '570 patent, and wherein nitric oxide

delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the '570 patent under 35 U.S.C. § 271(c).

128. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Mallinckrodt and Defendants as to liability for the infringement of the '570 patent claims. Defendants' actions have created in Mallinckrodt a reasonable apprehension of irreparable harm and loss.

129. On information and belief, if FDA approves Defendants' ANDA, Defendants' manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product before the expiration of the '570 patent will constitute willful infringement under 35 U.S.C. § 284.

130. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '570 patent, actively inducing infringement of the '570 patent, and/or contributing to the infringement by others of the '570 patent.

131. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

**COUNT III FOR PATENT INFRINGEMENT**
**(Infringement of the '904 Patent under 35 U.S.C. § 271(e)(2))**

132. Plaintiffs incorporate by reference paragraphs 1-131 as if fully set forth herein.

133. On information and belief, Defendants submitted Defendants' ANDA to FDA, and thereby seek FDA approval of Defendants' Proposed ANDA Product.

134. Defendants' Proposed ANDA Product infringes one or more claims of the '904 patent.

135. Defendants have infringed one or more claims of the '904 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA and thereby seeking FDA approval of a generic version of INOmax®, prior to the expiration of the '904 patent.

136. On information and belief, the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product prior to the expiration of the '904 Patent would infringe one or more claims of the '904 patent under 35 U.S.C. § 271(a), and/or Defendants would induce and/or contribute to the infringement of one or more claims of the '904 patent under 35 USC § 271(b) and/or (c).

137. Upon information and belief, Defendants have actual and/or constructive notice of the '904 patent since its publication on October 23, 2012, and nonetheless maintained Defendants' ANDA despite being aware that the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product prior to the expiration of the '904 patent would constitute an act of infringement.

138. Mallinckrodt will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '904 patent. Mallinckrodt does not have an adequate remedy at law and, considering the balance of hardships between Mallinckrodt and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

139. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '904 patent, actively inducing infringement of the '904 patent, and/or contributing to the infringement by others of the '904 patent.

140. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

**COUNT IV FOR DECLARATORY JUDGMENT**
**(Declaratory Judgement of Patent Infringement of the '904 Patent under 35 U.S.C. § 271 (a), (b), and/or (c))**

141. Plaintiffs incorporate by reference paragraphs 1-140 as if fully set forth herein.

142. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

143. On information and belief, if FDA approves Defendants' Proposed ANDA Product for use and sale in the United States, Defendants would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '904 patent under 35 U.S.C. § 271(a), in violation of Mallinckrodt's patent rights, by making, using, offering to sell, selling, and/or importing Defendants' Proposed ANDA Product for use and sale within the United States.

144. The manufacture, use, offer for sale, sale, and/or importation of Defendants' Proposed ANDA Product so labeled, if approved by FDA, will induce and/or contribute to the infringement of one or more claims of the '904 patent under 35 U.S.C. §§ 271(b) and/or (c), in violation of Mallinckrodt's patent rights.

145. On information and belief, Defendants have knowledge of the '904 patent and filed Defendants' ANDA seeking authorization to commercially manufacture, use, offer for sale, sell, and/or import into the United States Defendants' Proposed ANDA Product. On information and belief, if FDA approves Defendants' ANDA, physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '904 patent.

146. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the '904 patent with the requisite intent under 35 U.S.C. § 271(b).

147. On information and belief, if FDA approves Defendants' ANDA, Defendants will sell or offer to sell Defendants' Proposed ANDA Product specifically labeled to use a device as claimed in one or more of the claims of the '904 patent, wherein Defendants' Proposed ANDA Product is a material part of the inventions claimed in the '904 patent, wherein Defendants know that physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product for one or more of the inventions claimed in the '904 patent, and wherein nitric oxide delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the '904 patent under 35 U.S.C. § 271(c).

148. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Mallinckrodt and Defendants as to liability for the infringement of the '904 patent claims. Defendants' actions have created in Mallinckrodt a reasonable apprehension of irreparable harm and loss.

149. On information and belief, if FDA approves Defendants' ANDA, Defendants' manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product before the expiration of the '904 patent will constitute willful infringement under 35 U.S.C. § 284.

150. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the ’904 patent, actively inducing infringement of the ’904 patent, and/or contributing to the infringement by others of the ’904 patent.

151. This case is “exceptional,” as that term is used in 35 U.S.C. § 285.

**COUNT V FOR PATENT INFRINGEMENT**
**(Infringement of the ’209 Patent under 35 U.S.C. § 271(e)(2))**

152. Plaintiffs incorporate by reference paragraphs 1-151 as if fully set forth herein.

153. On information and belief, Defendants submitted Defendants’ ANDA to FDA, and thereby seek FDA approval of Defendants’ Proposed ANDA Product.

154. Defendants’ Proposed ANDA Product infringes one or more claims of the '209 patent.

155. Defendants have infringed one or more claims of the ’209 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants’ ANDA and thereby seeking FDA approval of a generic version of INOmax®, prior to the expiration of the ’209 patent.

156. On information and belief, the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants’ Proposed ANDA Product prior to the expiration of the ’209 Patent would infringe one or more claims of the ’209 patent under 35 U.S.C. § 271(a), and/or Defendants would induce and/or contribute to the infringement of one or more claims of the ’209 patent under 35 USC § 271(b) and/or (c).

157. Upon information and belief, Defendants had actual and/or constructive notice of the ’209 patent since its publication on November 5, 2013, and nonetheless maintained Defendants’ ANDA despite being aware that the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants’ Proposed ANDA Product prior to the expiration of the ’209 patent would constitute an act of infringement.

158. Mallinckrodt will be irreparably harmed if Defendants are not enjoined from infringing the ’209 patent. Mallinckrodt does not have an adequate remedy at law and, considering the balance of hardships between Mallinckrodt and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

159. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the ’209 patent, actively inducing infringement of the ’209 patent, and/or contributing to the infringement by others of the ’209 patent.

160. This case is “exceptional,” as that term is used in 35 U.S.C. § 285.

**COUNT VI FOR DECLARATORY JUDGMENT**
**(Declaratory Judgement of Patent Infringement of the '209 Patent under 35 U.S.C. § 271 (a), (b), and/or (c))**

161. Plaintiffs incorporate by reference paragraphs 1-160 as if fully set forth herein.

162. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

163. On information and belief, if FDA approves Defendants’ Proposed ANDA Product for use and sale in the United States, Defendants would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the ’209 patent under 35 U.S.C. § 271(a), in violation of Mallinckrodt’s patent rights, by making, using, offering to sell, selling, and/or importing Defendants’ Proposed ANDA Product for use and sale within the United States.

164. The manufacture, use, offer for sale, sale, and/or importation of Defendants’ Proposed ANDA Product so labeled, if approved by FDA, will induce and/or contribute to the

infringement of one or more claims of the ’209 patent under 35 U.S.C. §§ 271(b) and/or (c), in violation of Mallinckrodt’s patent rights.

165. On information and belief, Defendants have knowledge of the ’209 patent and filed Defendants’ ANDA seeking authorization to commercially manufacture, use, offer for sale, sell, and/or import into the United States Defendants’ Proposed ANDA Product. On information and belief, if FDA approves Defendants’ ANDA, physicians, health care providers, and/or patients will prescribe and/or use Defendants’ Proposed ANDA Product in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the ’209 patent.

166. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Defendants’ Proposed ANDA Product with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the ’209 patent with the requisite intent under 35 U.S.C. § 271(b).

167. On information and belief, if FDA approves Defendants’ ANDA, Defendants will sell or offer to sell Defendants’ Proposed ANDA Product specifically labeled for use in practicing one or more of the claims of the ’209 patent, wherein Defendants’ Proposed ANDA Product is a material part of the inventions claimed in the ’209 patent, wherein Defendants know that physicians, health care providers, and/or patients will prescribe and/or use Defendants’ Proposed ANDA Product for one or more of the inventions claimed in the ’209 patent, and wherein nitric oxide delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the ’209 patent under 35 U.S.C. § 271(c).

168. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Mallinckrodt and Defendants as to liability for the infringement of the '209 patent claims. Defendants' actions have created in Mallinckrodt a reasonable apprehension of irreparable harm and loss.

169. On information and belief, if FDA approves Defendants' ANDA, Defendants' manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product before the expiration of the '209 patent will constitute willful infringement under 35 U.S.C. § 284.

170. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '209 patent.

171. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

**COUNT VII FOR PATENT INFRINGEMENT**
**(Infringement of the '210 Patent under 35 U.S.C. § 271(e)(2))**

172. Plaintiffs incorporate by reference paragraphs 1-171 as if fully set forth herein.

173. On information and belief, Defendants submitted Defendants' ANDA to FDA, and thereby seek FDA approval of Defendants' Proposed ANDA Product.

174. Defendants' Proposed ANDA Product infringes one or more claims of the '210 patent.

175. Defendants have infringed one or more claims of the '210 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA and thereby seeking FDA approval of a generic version of INOmax®, prior to the expiration of the '210 patent.

176. On information and belief, the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product prior to the expiration of the '210 Patent would infringe one or more claims of the '210 patent under 35 U.S.C. § 271(a),

and/or Defendants would induce and/or contribute to the infringement of one or more claims of the '210 patent under 35 USC § 271(b) and/or (c).

177. Upon information and belief, Defendants had actual and/or constructive notice of the '210 patent since its publication on November 5, 2013, and nonetheless maintained Defendants' ANDA despite being aware that the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product prior to the expiration of the '210 patent would constitute an act of infringement.

178. Mallinckrodt will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '210 patent. Mallinckrodt does not have an adequate remedy at law and, considering the balance of hardships between Mallinckrodt and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

179. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '210 patent, actively inducing infringement of the '210 patent, and/or contributing to the infringement by others of the '210 patent.

180. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

**COUNT VIII FOR DECLARATORY JUDGMENT**
**(Declaratory Judgement of Patent Infringement of the '210 Patent under 35 U.S.C. § 271 (a), (b), and/or (c))**

181. Plaintiffs incorporate by reference paragraphs 1-180 as if fully set forth herein.

182. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

183. On information and belief, if FDA approves Defendants' Proposed ANDA Product for use and sale in the United States, Defendants would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '210 patent under 35 U.S.C. § 271(a), in violation of Mallinckrodt's patent rights, by making, using, offering to sell, selling, and/or importing Defendants' Proposed ANDA Product for use and sale within the United States.

184. The manufacture, use, offer for sale, sale, and/or importation of Defendants' Proposed ANDA Product so labeled, if approved by FDA, will induce and/or contribute to the infringement of one or more claims of the '210 patent under 35 U.S.C. §§ 271(b) and/or (c), in violation of Mallinckrodt's patent rights.

185. On information and belief, Defendants have knowledge of the '210 patent and filed Defendants' ANDA seeking authorization to commercially manufacture, use, offer for sale, sell, and/or import into the United States Defendants' Proposed ANDA Product. On information and belief, if FDA approves Defendants' ANDA, physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '210 patent.

186. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the '210 patent with the requisite intent under 35 U.S.C. § 271(b).

187. On information and belief, if FDA approves Defendants' ANDA, Defendants will sell or offer to sell Defendants' Proposed ANDA Product specifically labeled for use in practicing one or more of the claims of the '210 patent, wherein Defendants' Proposed ANDA Product is a

material part of the inventions claimed in the ’210 patent, wherein Defendants knows that physicians, health care providers, and/or patients will prescribe and/or use Defendants’ Proposed ANDA Product for one or more of the inventions claimed in the ’210 patent, and wherein nitric oxide delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the ’210 patent under 35 U.S.C. § 271(c).

188. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Mallinckrodt and Defendants as to liability for the infringement of the ’210 patent claims. Defendants’ actions have created in Mallinckrodt a reasonable apprehension of irreparable harm and loss.

189. On information and belief, if FDA approves Defendants’ ANDA, Defendants’ manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants’ Proposed ANDA Product before the expiration of the ’210 patent will constitute willful infringement under 35 U.S.C. § 284.

190. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the ’210 patent, actively inducing infringement of the ’210 patent, and/or contributing to the infringement by others of the '210 patent.

191. This case is “exceptional,” as that term is used in 35 U.S.C. § 285.

**COUNT IX FOR PATENT INFRINGEMENT**
**(Infringement of the ’6,794 Patent under 35 U.S.C. § 271(e)(2))**

192. Plaintiffs incorporate by reference paragraphs 1-191 as if fully set forth herein.

193. On information and belief, Defendants submitted Defendants’ ANDA to FDA, and thereby seek FDA approval of Defendants’ Proposed ANDA Product.

194. Defendants' Proposed ANDA Product infringes one or more claims of the '6,794 patent.

195. Defendants have infringed one or more claims of the '6,794 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA and thereby seeking FDA approval of a generic version of INOmax®, prior to the expiration of the '6,794 patent.

196. On information and belief, the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product prior to the expiration of the '6,794 Patent would infringe one or more claims of the '6,794 patent under 35 U.S.C. § 271(a), and/or Defendants would induce and/or contribute to the infringement of one or more claims of the '6,794 patent under 35 USC § 271(b) and/or (c).

197. Upon information and belief, Defendants had actual and/or constructive notice of the '6,794 patent since its publication on July 15, 2014, and nonetheless maintained Defendants' ANDA despite being aware that the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product prior to the expiration of the '6,794 patent would constitute an act of infringement.

198. Mallinckrodt will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '6,794 patent. Mallinckrodt does not have an adequate remedy at law and, considering the balance of hardships between Mallinckrodt and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

199. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '6,794 patent, actively inducing infringement of the '6,794 patent, and/or contributing to the infringement by others of the '6,794 patent.

200. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

**COUNT X FOR DECLARATORY JUDGMENT**
**(Declaratory Judgement of Patent Infringement of the '6,794 Patent under 35 U.S.C. § 271 (a), (b), and/or (c))**

201. Plaintiffs incorporate by reference paragraphs 1-200 as if fully set forth herein.

202. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

203. On information and belief, if FDA approves Defendants' Proposed ANDA Product for use and sale in the United States, Defendants would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '6,794 patent under 35 U.S.C. § 271(a), in violation of Mallinckrodt's patent rights, by making, using, offering to sell, selling, and/or importing Defendants' Proposed ANDA Product for use and sale within the United States.

204. The manufacture, use, offer for sale, sale, and/or importation of Defendants' Proposed ANDA Product so labeled, if approved by FDA, will induce and/or contribute to the infringement of one or more claims of the '6,794 patent under 35 U.S.C. §§ 271(b) and/or (c), in violation of Mallinckrodt's patent rights.

205. On information and belief, Defendants have knowledge of the '6,794 patent and filed Defendants' ANDA seeking authorization to commercially manufacture, use, offer for sale, sell, and/or import into the United States Defendants' Proposed ANDA Product. On information and belief, if FDA approves Defendants' ANDA, physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '6,794 patent.

206. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the '6,794 patent with the requisite intent under 35 U.S.C. § 271(b).

207. On information and belief, if FDA approves Defendants' ANDA, Defendants will sell or offer to sell Defendants' Proposed ANDA Product specifically labeled for use in practicing one or more of the claims of the '6,794 patent, wherein Defendants' Proposed ANDA Product is a material part of the inventions claimed in the '6,794 patent, wherein Defendants know that physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product for one or more of the inventions claimed in the '6,794 patent, and wherein nitric oxide delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the '6,794 patent under 35 U.S.C. § 271(c).

208. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Mallinckrodt and Defendants as to liability for the infringement of the '6,794 patent claims. Defendants' actions have created in Mallinckrodt a reasonable apprehension of irreparable harm and loss.

209. On information and belief, if FDA approves Defendants' ANDA, Defendants' manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product before the expiration of the '6,794 patent will constitute willful infringement under 35 U.S.C. § 284.

210. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '6,794 patent, actively inducing infringement of the '6,794 patent, and/or contributing to the infringement by others of the '6,794 patent.

211. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

**COUNT XI FOR PATENT INFRINGEMENT**
**(Infringement of the '795 Patent under 35 U.S.C. § 271(e)(2))**

212. Plaintiffs incorporate by reference paragraphs 1-211 as if fully set forth herein.

213. On information and belief, Defendants submitted Defendants' ANDA to FDA, and thereby seek FDA approval of Defendants' Proposed ANDA Product.

214. Defendants' Proposed ANDA Product infringes one or more claims of the '795 patent.

215. Defendants have infringed one or more claims of the '795 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA and thereby seeking FDA approval of a generic version of INOmax®, prior to the expiration of the '795 patent.

216. On information and belief, the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product prior to the expiration of the '795 Patent would infringe one or more claims of the '795 patent under 35 U.S.C. § 271(a), and/or Defendants would induce and/or contribute to the infringement of one or more claims of the '795 patent under 35 USC § 271(b) and/or (c).

217. Upon information and belief, Defendants had actual and/or constructive notice of the '795 patent since its publication on July 15, 2014, and nonetheless maintained Defendants' ANDA despite being aware that the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product prior to the expiration of the '795 patent would constitute an act of infringement.

218. Mallinckrodt will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '795 patent. Mallinckrodt does not have an adequate remedy at law and, considering the balance of hardships between Mallinckrodt and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

219. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '795 patent, actively inducing infringement of the '795 patent, and/or contributing to the infringement by others of the '795 patent.

220. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

**COUNT XII FOR DECLARATORY JUDGMENT**
**(Declaratory Judgement of Patent Infringement of the '795 Patent under 35 U.S.C. § 271 (a), (b), and/or (c))**

221. Plaintiffs incorporate by reference paragraphs 1-220 as if fully set forth herein.

222. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

223. On information and belief, if FDA approves Defendants' Proposed ANDA Product for use and sale in the United States, Defendants would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '795 patent under 35 U.S.C. § 271(a), in violation of Mallinckrodt's patent rights, by making, using, offering to sell, selling, and/or importing Defendants' Proposed ANDA Product for use and sale within the United States.

224. The manufacture, use, offer for sale, sale, and/or importation of Defendants' Proposed ANDA Product so labeled, if approved by FDA, will induce and/or contribute to the

infringement of one or more claims of the ’795 patent under 35 U.S.C. §§ 271(b) and/or (c), in violation of Mallinckrodt’s patent rights.

225. On information and belief, Defendants have knowledge of the ’795 patent and filed Defendants’ ANDA seeking authorization to commercially manufacture, use, offer for sale, sell, and/or import into the United States Defendants’ Proposed ANDA Product. On information and belief, if FDA approves Defendants’ ANDA, physicians, health care providers, and/or patients will prescribe and/or use Defendants’ Proposed ANDA Product in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the ’795 patent.

226. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Defendants’ Proposed ANDA Product with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the ’795 patent with the requisite intent under 35 U.S.C. § 271(b).

227. On information and belief, if FDA approves Defendants’ ANDA, Defendants will sell or offer to sell Defendants’ Proposed ANDA Product specifically labeled for use in practicing one or more of the claims of the ’795 patent, wherein Defendants’ Proposed ANDA Product is a material part of the inventions claimed in the ’795 patent, wherein Defendants know that physicians, health care providers, and/or patients will prescribe and/or use Defendants’ Proposed ANDA Product for one or more of the inventions claimed in the ’795 patent, and wherein nitric oxide delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the ’795 patent under 35 U.S.C. § 271(c).

228. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Mallinckrodt and Defendants as to liability for the infringement of the '795 patent claims. Defendants' actions have created in Mallinckrodt a reasonable apprehension of irreparable harm and loss.

229. On information and belief, if FDA approves Defendants' ANDA, Defendants' manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product before the expiration of the '795 patent will constitute willful infringement under 35 U.S.C. § 284.

230. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '795 patent, actively inducing infringement of the '795 patent, and/or contributing to the infringement by others of the '795 patent.

231. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

**COUNT XIII FOR PATENT INFRINGEMENT**
**(Infringement of the '911 Patent under 35 U.S.C. § 271(e)(2))**

232. Plaintiffs incorporate by reference paragraphs 1-231 as if fully set forth herein.

233. On information and belief, Defendants submitted Defendants' ANDA to FDA, and thereby seek FDA approval of Defendants' Proposed ANDA Product.

234. Defendants' Proposed ANDA Product infringes one or more claims of the '911 patent.

235. Defendants have infringed one or more claims of the '911 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA and thereby seeking FDA approval of a generic version of INOmax®, prior to the expiration of the '911 patent.

236. On information and belief, the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product prior to the expiration

of the '911 Patent would infringe one or more claims of the '911 patent under 35 U.S.C. § 271(a), and/or Defendants would induce and/or contribute to the infringement of one or more claims of the '911 patent under 35 USC § 271(b) and/or (c).

237. Upon information and belief, Defendants had actual and/or constructive notice of the '911 patent since its publication on February 23, 2016, and nonetheless maintained Defendants' ANDA despite being aware that the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product prior to the expiration of the '911 patent would constitute an act of infringement.

238. Mallinckrodt will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '911 patent. Mallinckrodt does not have an adequate remedy at law and, considering the balance of hardships between Mallinckrodt and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

239. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '911 patent, actively inducing infringement of the '911 patent, and/or contributing to the infringement by others of the '911 patent.

240. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

**COUNT XIV FOR DECLARATORY JUDGMENT**
**(Declaratory Judgement of Patent Infringement of the '911 Patent under 35 U.S.C. § 271 (a), (b), and/or (c))**

241. Plaintiffs incorporate by reference paragraphs 1-240 as if fully set forth herein.

242. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

243. On information and belief, if FDA approves Defendants' Proposed ANDA Product for use and sale in the United States, Defendants would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '911 patent under 35 U.S.C. § 271(a), in violation of Mallinckrodt's patent rights, by making, using, offering to sell, selling, and/or importing Defendants' Proposed ANDA Product for use and sale within the United States.

244. The manufacture, use, offer for sale, sale, and/or importation of Defendants' Proposed ANDA Product so labeled, if approved by FDA, will induce and/or contribute to the infringement of one or more claims of the '911 patent under 35 U.S.C. §§ 271(b) and/or (c), in violation of Mallinckrodt's patent rights.

245. On information and belief, Defendants have knowledge of the '911 patent and filed Defendants' ANDA seeking authorization to commercially manufacture, use, offer for sale, sell, and/or import into the United States Defendants' Proposed ANDA Product. On information and belief, if FDA approves Defendants' ANDA, physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '911 patent.

246. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the '911 patent with the requisite intent under 35 U.S.C. § 271(b).

247. On information and belief, if FDA approves Defendants' ANDA, Defendants will sell or offer to sell Defendants' Proposed ANDA Product specifically labeled for use in practicing one or more of the claims of the '911 patent, wherein Defendants' Proposed ANDA Product is a

material part of the inventions in the ’911 patent, wherein Defendants know that physicians, health care providers, and/or patients will prescribe and/or use Defendants’ Proposed ANDA Product for one or more of the inventions claimed in the ’911 patent, and wherein nitric oxide delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the ’911 patent under 35 U.S.C. § 271(c).

248. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Mallinckrodt and Defendants as to liability for the infringement of the ’911 patent claims. Defendants’ actions have created in Mallinckrodt a reasonable apprehension of irreparable harm and loss.

249. On information and belief, if FDA approves Defendants’ ANDA, Defendants’ manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants’ Proposed ANDA Product before the expiration of the ’911 patent will constitute willful infringement under 35 U.S.C. § 284.

250. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the ’911 patent, actively inducing infringement of the '911 patent, and/or contributing to the infringement by others of the ’911 patent.

251. This case is “exceptional,” as that term is used in 35 U.S.C. § 285.

**COUNT XV FOR PATENT INFRINGEMENT**
**(Infringement of the ’9,794 Patent under 35 U.S.C. § 271(e)(2))**

252. Plaintiffs incorporate by reference paragraphs 1-251 as if fully set forth herein.

253. On information and belief, Defendants submitted Defendants’ ANDA to FDA, and thereby seek FDA approval of Defendants’ Proposed ANDA Product.

254. Defendants' Proposed ANDA Product infringes one or more claims of the '9,794 patent.

255. Defendants have infringed one or more claims of the '9,794 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA and thereby seeking FDA approval of a generic version of INOmax®, prior to the expiration of the '9,794 patent.

256. On information and belief, the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product prior to the expiration of the '9,794 Patent would infringe one or more claims of the '9,794 patent under 35 U.S.C. § 271(a), and/or Defendants would induce and/or contribute to the infringement of one or more claims of the '9,794 patent under 35 USC § 271(b) and/or (c).

257. Upon information and belief, Defendants had actual and/or constructive notice of the '9,794 patent since its publication on March 8, 2016, and nonetheless maintained Defendants' ANDA despite being aware that the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product prior to the expiration of the '9,794 patent would constitute an act of infringement.

258. Mallinckrodt will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '9,794 patent. Mallinckrodt does not have an adequate remedy at law and, considering the balance of hardships between Mallinckrodt and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

259. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '9,794 patent, actively inducing infringement of the '9,794 patent, and/or contributing to the infringement by others of the '9,794 patent.

260. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

**COUNT XVI FOR DECLARATORY JUDGMENT**
**(Declaratory Judgement of Patent Infringement of the '9,794 Patent under 35 U.S.C. § 271 (a), (b), and/or (c))**

261. Plaintiffs incorporate by reference paragraphs 1-260 as if fully set forth herein.

262. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

263. On information and belief, if FDA approves Defendants' Proposed ANDA Product for use and sale in the United States, Defendants would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '9,794 patent under 35 U.S.C. § 271(a), in violation of Mallinckrodt's patent rights, by making, using, offering to sell, selling, and/or importing Defendants' Proposed ANDA Product for use and sale within the United States.

264. The manufacture, use, offer for sale, sale, and/or importation of Defendants' Proposed ANDA Product so labeled, if approved by FDA, will induce and/or contribute to the infringement of one or more claims of the '9,794 patent under 35 U.S.C. §§ 271(b) and/or (c), in violation of Mallinckrodt's patent rights.

265. On information and belief, Defendants have knowledge of the '9,794 patent and filed Defendants' ANDA seeking authorization to commercially manufacture, use, offer for sale, sell, and/or import into the United States Defendants' Proposed ANDA Product. On information and belief, if FDA approves Defendants' ANDA, physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '9,794 patent.

266. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the '9,794 patent with the requisite intent under 35 U.S.C. § 271(b).

267. On information and belief, if FDA approves Defendants' ANDA, Defendants will sell or offer to sell Defendants' Proposed ANDA Product specifically labeled for use in practicing one or more of the methods of the '9,794 patent, wherein Defendants' Proposed ANDA Product is a material part of the methods claimed in the '9,794 patent, wherein Defendants know that physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product for one or more of the methods claimed in the '9,794 patent, and wherein nitric oxide delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the '9,794 patent under 35 U.S.C. § 271(c).

268. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Mallinckrodt and Defendants as to liability for the infringement of the '9,794 patent claims. Defendants' actions have created in Mallinckrodt a reasonable apprehension of irreparable harm and loss.

269. On information and belief, if FDA approves Defendants' ANDA, Defendants' manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product before the expiration of the '9,794 patent will constitute willful infringement under 35 U.S.C. § 284.

270. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '9,794 patent, actively inducing infringement of the '9,794 patent, and/or contributing to the infringement by others of the '9,794 patent.

271. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

**COUNT XVII FOR PATENT INFRINGEMENT**
**(Infringement of the '802 Patent under 35 U.S.C. § 271(e)(2))**

272. Plaintiffs incorporate by reference paragraphs 1-271 as if fully set forth herein.

273. On information and belief, Defendants submitted Defendants' ANDA to FDA, and thereby seek FDA approval of Defendants' Proposed ANDA Product.

274. Defendants' Proposed ANDA Product infringes one or more claims of the '802 patent.

275. Defendants have infringed one or more claims of the '802 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA and thereby seeking FDA approval of a generic version of INOmax®, prior to the expiration of the '802 patent.

276. On information and belief, the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product prior to the expiration of the '802 Patent would infringe one or more claims of the '802 patent under 35 U.S.C. § 271(a), and/or Defendants would induce and/or contribute to the infringement of one or more claims of the '802 patent under 35 USC § 271(b) and/or (c).

277. Upon information and belief, Defendants had actual and/or constructive notice of the '802 patent since its publication on March 29, 2016, and nonetheless maintained Defendants' ANDA despite being aware that the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product prior to the expiration of the '802 patent would constitute an act of infringement.

278. Mallinckrodt will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '802 patent. Mallinckrodt does not have an adequate remedy at law and, considering the balance of hardships between Mallinckrodt and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

279. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '802 patent, actively inducing infringement of the '802 patent, and/or contributing to the infringement by others of the '802 patent.

280. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

**COUNT XVIII FOR DECLARATORY JUDGMENT**
**(Declaratory Judgement of Patent Infringement of the '802 Patent under 35 U.S.C. § 271 (a), (b), and/or (c))**

281. Plaintiffs incorporate by reference paragraphs 1-280 as if fully set forth herein.

282. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

283. On information and belief, if FDA approves Defendants' Proposed ANDA Product for use and sale in the United States, Defendants would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '802 patent under 35 U.S.C. § 271(a), in violation of Mallinckrodt's patent rights, by making, using, offering to sell, selling, and/or importing Defendants' Proposed ANDA Product for use and sale within the United States.

284. The manufacture, use, offer for sale, sale, and/or importation of Defendants' Proposed ANDA Product so labeled, if approved by FDA, will induce and/or contribute to the

infringement of one or more claims of the ’802 patent under 35 U.S.C. §§ 271(b) and/or (c), in violation of Mallinckrodt’s patent rights.

285. On information and belief, Defendants have knowledge of the ’802 patent and filed Defendants’ ANDA seeking authorization to commercially manufacture, use, offer for sale, sell, and/or import into the United States Defendants’ Proposed ANDA Product. On information and belief, if FDA approves Defendants’ ANDA, physicians, health care providers, and/or patients will prescribe and/or use Defendants’ Proposed ANDA Product in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '802 patent.

286. On information and belief, Defendants knows and intends that physicians, health care providers, and/or patients will prescribe and/or use Defendants’ Proposed ANDA Product with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the ’802 patent with the requisite intent under 35 U.S.C. § 271(b).

287. On information and belief, if FDA approves Defendants’ ANDA, Defendants will sell or offer to sell Defendants’ Proposed ANDA Product specifically labeled for use in practicing one or more of the claims of the ’802 patent, wherein Defendants’ Proposed ANDA Product is a material part of the inventions claimed in the ’802 patent, wherein Defendants knows that physicians, health care providers, and/or patients will prescribe and/or use Defendants’ Proposed ANDA Product for one or more of the inventions claimed in the ’802 patent, and wherein nitric oxide delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the ’802 patent under 35 U.S.C. § 271(c).

288. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Mallinckrodt and Defendants as to liability for the infringement of the '802 patent claims. Defendants' actions have created in Mallinckrodt a reasonable apprehension of irreparable harm and loss.

289. On information and belief, if FDA approves Defendants' ANDA, Defendants' manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product before the expiration of the '802 patent will constitute willful infringement under 35 U.S.C. § 284.

290. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '802 patent, actively inducing infringement of the '802 patent, and/or contributing to the infringement by others of the '802 patent.

291. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

**COUNT XIX FOR PATENT INFRINGEMENT**
**(Infringement of the '993 Patent under 35 U.S.C. § 271(e)(2))**

292. Plaintiffs incorporate by reference paragraphs 1-291 as if fully set forth herein.

293. On information and belief, Defendants submitted Defendants' ANDA to FDA, and thereby seek FDA approval of Defendants' Proposed ANDA Product.

294. Defendants' Proposed ANDA Product infringes one or more claims of the '993 patent.

295. Defendants have infringed one or more claims of the '993 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA and thereby seeking FDA approval of a generic version of INOmax®, prior to the expiration of the '993 patent.

296. On information and belief, the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product prior to the expiration

of the '993 Patent would infringe one or more claims of the '993 patent under 35 U.S.C. § 271(a), and/or Defendants would induce and/or contribute to the infringement of one or more claims of the '993 patent under 35 USC § 271(b) and/or (c).

297. Upon information and belief, Defendants had actual and/or constructive notice of the '993 patent since its publication on August 9, 2016, and nonetheless maintained Defendants' ANDA despite being aware that the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product prior to the expiration of the '993 patent would constitute an act of infringement.

298. Mallinckrodt will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '993 patent. Mallinckrodt does not have an adequate remedy at law and, considering the balance of hardships between Mallinckrodt and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

299. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '993 patent, actively inducing infringement of the '993 patent, and/or contributing to the infringement by others of the '993 patent.

300. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

**COUNT XX FOR DECLARATORY JUDGMENT**
**(Declaratory Judgement of Patent Infringement of the '993 Patent under 35 U.S.C. § 271 (a), (b), and/or (c))**

301. Plaintiffs incorporate by reference paragraphs 1-300 as if fully set forth herein.

302. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

303. On information and belief, if FDA approves Defendants' Proposed ANDA Product for use and sale in the United States, Defendants would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '993 patent under 35 U.S.C. § 271(a), in violation of Mallinckrodt's patent rights, by making, using, offering to sell, selling, and/or importing Defendants' Proposed ANDA Product for use and sale within the United States.

304. The manufacture, use, offer for sale, sale, and/or importation of Defendants' Proposed ANDA Product so labeled, if approved by FDA, will induce and/or contribute to the infringement of one or more claims of the '993 patent under 35 U.S.C. §§ 271(b) and/or (c), in violation of Mallinckrodt's patent rights.

305. On information and belief, Defendants have knowledge of the '993 patent and filed Defendants' ANDA seeking authorization to commercially manufacture, use, offer for sale, sell, and/or import into the United States Defendants' Proposed ANDA Product. On information and belief, if FDA approves Defendants' ANDA, physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '993 patent.

306. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the '993 patent with the requisite intent under 35 U.S.C. § 271(b).

307. On information and belief, if FDA approves Defendants' ANDA, Defendants will sell or offer to sell Defendants' Proposed ANDA Product specifically labeled for use in practicing one or more of the claims of the '993 patent, wherein Defendants' Proposed ANDA Product is a

material part of the inventions claimed in the '993 patent, wherein Defendants knows that physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product for one or more of the inventions claimed in the '993 patent, and wherein nitric oxide delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the '993 patent under 35 U.S.C. § 271(c).

308. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Mallinckrodt and Defendants as to liability for the infringement of the '993 patent claims. Defendants' actions have created in Mallinckrodt a reasonable apprehension of irreparable harm and loss.

309. On information and belief, if FDA approves Defendants' ANDA, Defendants' manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product before the expiration of the '993 patent will constitute willful infringement under 35 U.S.C. § 284.

310. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '993 patent, actively inducing infringement of the '993 patent, and/or contributing to the infringement by others of the '993 patent.

311. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

**COUNT XXI FOR PATENT INFRINGEMENT**
**(Infringement of the '741 Patent under 35 U.S.C. § 271(e)(2))**

312. Plaintiffs incorporate by reference paragraphs 1-311 as if fully set forth herein.

313. On information and belief, Defendants submitted Defendants' ANDA to FDA, and thereby seek FDA approval of Defendants' Proposed ANDA Product.

314. Claims 24-30, and 33 of the '741 patent were not subject to the judgment in the *Praxair* litigation.

315. Defendants' Proposed ANDA Product infringes one or more of claims 24-30, and 33 of the '741 patent.

316. Defendants have infringed one or more of claims 24-30, and 33 of the '741 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA and thereby seeking FDA approval of a generic version of INOmax®, prior to the expiration of the '741 patent.

317. On information and belief, the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product prior to the expiration of the '741 Patent would infringe one or more of claims 24-30, and 33 of the '741 patent under 35 U.S.C. § 271(a), and/or Defendants would induce and/or contribute to the infringement of one or more of claims 24-30, and 33 of the '741 patent under 35 USC § 271(b) and/or (c).

318. Upon information and belief, Defendants had actual and/or constructive notice of the '741 patent since its publication on August 5, 2014, and nonetheless maintained Defendants' ANDA despite being aware that the manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product prior to the expiration of the '741 patent would constitute an act of infringement.

319. Mallinckrodt will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of, one or more of claims 24-30, and 33 of the '741 patent. Mallinckrodt does not have an adequate remedy at law and, considering the balance of hardships between Mallinckrodt and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

320. Defendants acted without a reasonable basis for believing that they would not be liable for infringing one or more of claims 24-30, and 33 of the '741 patent, actively inducing infringement of one or more of claims 24-30, and 33 of the '741 patent, and/or contributing to the infringement by others of one or more of claims 24-30, and 33 of the '741 patent.

321. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

**COUNT XXII FOR DECLARATORY JUDGMENT**
**(Declaratory Judgement of Patent Infringement of the '741 Patent under 35 U.S.C. § 271 (a), (b), and/or (c))**

322. Plaintiffs incorporate by reference paragraphs 1-321 as if fully set forth herein.

323. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

324. On information and belief, if FDA approves Defendants' Proposed ANDA Product for use and sale in the United States, Defendants would directly infringe, literally and/or through the doctrine of equivalents, one or more of claims 24-30, and 33 of the '741 patent under 35 U.S.C. § 271(a), in violation of Mallinckrodt's patent rights, by making, using, offering to sell, selling, and/or importing Defendants' Proposed ANDA Product for use and sale within the United States.

325. The manufacture, use, offer for sale, sale, and/or importation of Defendants' Proposed ANDA Product so labeled, if approved by FDA, will induce and/or contribute to the infringement of one or more of claims 2, 3, 5, 6, 8, 10-16, and 19-44, and at least claim 24 of the '741 patent under 35 U.S.C. §§ 271(b) and/or (c), in violation of Mallinckrodt's patent rights.

326. On information and belief, Defendants have knowledge of the '741 patent and filed Defendants' ANDA seeking authorization to commercially manufacture, use, offer for sale,

sell, and/or import into the United States Defendants' Proposed ANDA Product. On information and belief, if FDA approves Defendants' ANDA, physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more of claims 24-30, and 33 of the '741 patent.

327. On information and belief, Defendants knows and intends that physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of claims 24-30, and 33 of the '741 patent with the requisite intent under 35 U.S.C. § 271(b).

328. On information and belief, if FDA approves Defendants' ANDA, Defendants will sell or offer to sell Defendants' Proposed ANDA Product specifically labeled for use in practicing one or more of claims 24-30, and 33 of the '741 patent, wherein Defendants' Proposed ANDA Product is a material part of the methods claimed in one or more of claims 24-30, and 33 of the '741 patent, wherein Defendants know that physicians, health care providers, and/or patients will prescribe and/or use Defendants' Proposed ANDA Product for one or more of the methods claimed in one or more of claims 24-30, and 33 of the '741 patent, and wherein nitric oxide delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of one or more of claims 24-30, and 33 of the '741 patent under 35 U.S.C. § 271(c).

329. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Mallinckrodt and Defendants as to liability for the infringement

of one or more of claims 24-30, and 33 of the '741 patent claims. Defendants' actions have created in Mallinckrodt a reasonable apprehension of irreparable harm and loss.

330. On information and belief, if FDA approves Defendants' ANDA, Defendants' manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' Proposed ANDA Product before the expiration of the '741 patent will constitute willful infringement under 35 U.S.C. § 284.

331. Defendants acted without a reasonable basis for believing that they would not be liable for infringing one or more of claims 24-30, and 33 of the '741 patent, actively inducing infringement of one or more of claims 24-30, and 33 of the '741 patent, and/or contributing to the infringement by others of one or more of claims 24-30, and 33 of the '741 patent.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Defendants have infringed one or more claims of one or more of the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A);

B. A Judgment and Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Defendants' ANDA shall be no be earlier than the expiration date of the latest to expire of any Patents-in-Suit adjudged to be infringed by Defendants, including the expiration of any applicable extensions or regulatory exclusivities;

C. A Judgment and Order that Defendants, their directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, are permanently enjoined from commercially manufacturing, using, offering to sell, selling, marketing, distributing, or importing Defendants' Proposed ANDA Product and any other product that infringes or induces or contributes to the infringement of the Patents-in-Suit, prior to

the expiration of any of the Patents-in-Suit adjudged to be infringed, including any exclusivities or extensions to which Plaintiffs are or become entitled;

D. A Judgment declaring that making, using, selling, offering to sell, or importing Defendants' Proposed ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the Patents-in-Suit pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

E. A declaration under 28 U.S.C. § 2201 that, if Defendants, their officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with them or on their behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of Defendants' Proposed ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

F. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' Proposed ANDA Product, or any product that infringes the Patents-in-Suit, or induces or contributes to such conduct, prior to the expiration of any of the Patents-in-Suit adjudged to be infringed, including the expiration of any additional exclusivity period applicable to that patent;

G. A finding that this case is an exceptional case and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

H. Costs and expenses in this action; and

I. Such other and further relief as this Court deems just and proper.

*/s/ Frederick L. Cottrell, III*

Frederick L. Cottrell, III (#2555)
Kelly E. Farnan (#4395)
Sara M. Metzler (#6509)
Richards, Layton & Finger, P.A.
One Rodney Square
920 N. King Street
Wilmington, DE 19801
(302) 651-7700
cottrell@rlf.com
farnan@rlf.com
metzler@rlf.com

*Attorneys for Plaintiffs*

OF COUNSEL:

Dennies Varughese, Pharm. D.
Adam C. LaRock
Robert Niemeier
Christina Dashe
Alex Alfano
Grace Tuyiringire
Ryan Conkin
David Silversmith
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C
1100 New York Avenue NW
Suite 600
Washington, DC 20005
(202) 371-2600

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